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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,557	07/18/2002	Xuebao Li	2577-139	3290

6449 7590 12/17/2004

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,557	LI ET AL.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2* is/are allowed.

6)☒ Claim(s) *1 and 3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 April 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/9/04, 4/1/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *seq. search result*.

DETAILED ACTION

1. Claims 1-3 are pending and are examined in the present office action. Nucleotides 1 through 816 of SEQ ID NO:2 are included in the examination.

Specification

2. The specification is objected to because SEQ ID NO:2 of the sequence listing is disclosed as being a DNA molecule from Arabidopsis, but the specification discloses that SEQ ID NO:2 is isolated from cotton (page 4, lines 12-13).

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a promoter that is cotton fiber-specific comprising the promoter of the cotton actin gene CFACT1 or a promoter that is cotton fiber-specific comprising an active fragment of nucleotides 1 through 816 of SEQ ID NO:2.

Applicants isolated a cDNA clone from a cDNA library made from young cotton fibers which was subsequently sequenced and identified as a CFACT1 cDNA fragment (pages 9 and 10). This fragment was used to isolate the genomic sequence which is listed as SEQ ID NO:2 (pages 13-14). Applicants disclose that the first 0.8 kb of SEQ ID NO:2 comprise the promoter.

The Applicants do not identify essential regions of the CFACT1 promoter sequence comprising bases 1 to 816 of SEQ ID NO:2, nor do Applicants describe any fragments of said sequences that has the activity of bases 1 to 816 of SEQ ID NO:2. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of CFACT1 promoter sequences that direct expression in the same spatial and temporal pattern as nucleotides 1 to 816 of SEQ ID NO:2 or Applicants fail to describe promoter fragments of bases 1 to 816 of SEQ ID NO:2 that direct expression in the same spatial and temporal pattern as bases 1 to 816 of SEQ ID NO:2.

Applicants only describe a single promoter sequence comprising bases 1 to 816 of SEQ ID NO:2. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the promoter sequence of bases 1 to 816 of SEQ ID NO:2, it remains unclear what features identify a cotton fiber-specific promoter of bases 1 to 816 of SEQ ID NO:2. Since the genus of CFACT1 promoter sequences comprising bases 1 to 816 of SEQ ID NO:2 has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Scope of Enablement

4. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cotton fiber-specific promoter comprising bases 1 to 816 of SEQ ID NO:2, does not reasonably provide enablement for any cotton fiber-specific promoter comprising any promoter of any cotton fiber-specific actin gene CFACT1 or any promoter comprising any fragment of bases 1 to 816 of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of

experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a promoter that is cotton fiber-specific comprising the promoter of the cotton actin gene CFACT1 or a promoter that is cotton fiber-specific comprising an active fragment of nucleotides 1 through 816 of SEQ ID NO:2.

Applicants isolated a cDNA clone from a cDNA library made from young cotton fibers which was subsequently sequenced and identified as a CFACT1 cDNA fragment (pages 9 and 10). This fragment was used to isolate the genomic sequence which is listed as SEQ ID NO:2 (pages 13-14). Applicants disclose that the first 0.8 kb of SEQ ID NO:2 comprise the promoter, which was subsequently operably linked to the GUS reporter gene and transformed into cotton and tobacco (pages 14-19, Example 3). Transgenic cotton exhibited GUS activity only in young fibers and transgenic tobacco exhibited GUS activity in seeds (paragraph bridging pages 18 and 19).

The state-of-the-art teaches using pieces of a promoter that do not contain the full compliment of cis-acting elements, will not produce the expression profile as observed using the whole promoter fragment. Kagaya et al (1995, Mol. Gen. Genet. 248 :668-674) teach the rice chloroplastic aldolase promoter contains two elements, one of which acts as a negative element while the other acts as a positive element that confers developmentally regulated mesophyll cell specific expression. Removal of either of these regions changes the normal expression pattern

(page 670, left column). Kagaya et al also teach that the promoter contains an element that serves as a target for light induction (abstract).

Benfey et al (1990, Science 250:959-966) teach that the 35S CaMV promoter consists of domains that individually regulate spatial expression within plants. "The combination of each of the five B subdomains with domain A results in an expression pattern that differs from that of the individual subdomains or domain A" (page 961, left column, 2nd paragraph). In other words, deleting a required domain will jeopardize the proper spatial and temporal expression pattern. In addition, Benfey et al (1989, EMBO J, 8(8):2195-2202; page 2200, left column 2nd paragraph) teach that not only are the promoter domains important for specifying proper spatial and temporal expression but that when all domains were present, the quantity of expression increased.

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of bases 1 to 816 of SEQ ID NO:2 as probes or by designing primers to undisclosed regions of bases 1 to 816 of SEQ ID NO:2 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed direct expression in cotton fibers.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claim 3 is rejected under 35 U.S.C. 102(a) as being anticipated by Miki et al (October 1999, WO 99/53067-A2).

The claim is drawn to a promoter that is cotton fiber-specific comprising an active fragment of the promoter sequence of nucleotides 1 through 816 of SEQ ID NO:2.

Miki et al disclose SEQ ID NO:9 which comprises a promoter set forth in bases 1-5514 of SEQ ID NO:9, and said region exhibits 49% identity with Applicants' nucleotides 1-816 of SEQ ID NO:2. The sequence of Miki et al directs expression in the seed coat of soybean and also in trichomes. It would be inherent that the promoter sequence of Miki et al would express in cotton fibers given that both cotton fibers and trichomes comprise cells of the epidermis of seeds and given that Applicants' sequence also directs expression in the seed coat of non-cotton plants, e.g., of tobacco (paragraph bridging pages 18 and 19). Given Applicants' definition of fragment, "A fragment can comprise excisions, deletions, truncations or substitutions of the sequence of nucleotides 1-816 of SEQ ID NO: 2, or a combination of these" (page 7, lines 19-22), and as such, Miki et al anticipate the claimed invention.

6. Claim 2 is deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of bases 1 to 816 of SEQ ID NO:2.

7. Claim 2 is allowed.

8. Claims 1 and 3 are not allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
December 8, 2004

DAVID H. KRUSE, PH.D.
PATENT EXAMINER

102(a) for Clm 3

RESULT 6
AAZ29911/c
ID AAZ29911 standard; DNA; 8310 BP.
XX
AC AAZ29911;
XX
DT 26-JAN-2000 (first entry)
XX
DE cDNA encoding a SC4 protein of soybean.
XX
KW Promoter; seed coat specificity; SC4 protein; herbicide resistance gene;
KW viral coat protein; biological control; Bt toxin; seed taste; ss.
XX
OS Glycine max.
XX
FH Key Location/Qualifiers
FT promoter 1. .5514
FT /*tag= a
FT /note= "claimed"
XX
PN WO9953067-A2.
XX
PD 21-OCT-1999.
XX
PF 13-APR-1999; 99WO-CA000293.
XX
PR 13-APR-1998; 98US-00059090.
XX
PA (MIAC) CANADA MIN AGRIC & AGRI-FOOD CANADA.
XX
PI Miki B, Gijzen M, Miller S, Bowman L, Batchelor A, Hu M;
PI Boutilier K;
XX
DR WPI; 1999-611304/52.
XX
PT Novel promoter sequences and genes useful for inducing expression of
PT genes in plant seed coats.
XX
PS Claim 36; Page 147-155; 155pp; English.
XX
CC The present sequence encodes a SC4 protein. The promoter of this gene is
CC differentially expressed in seed coat tissues, specifically within the
CC outer integument, the inner integument, the thick walled parenchyma, the
CC thin walled parenchyma, the endothelium, the hourglass cells, the
CC palisade, the stellate parenchyma, or the membranous endocarp associated
CC with the seed coat. The seed-coat promoters may be used to express
CC proteins of interest in seed coat tissues. Genes of interest include but
CC are not restricted to herbicide resistance genes, genes encoding viral
CC coat proteins, or genes encoding proteins conferring biological control
CC of pests or pathogens, e.g. a Bt toxin. Other genes that may be expressed
CC include proteins that alter the taste of the seed and/or affect the
CC nutritive value of the seed
XX
SQ Sequence 8310 BP; 2807 A; 1283 C; 1265 G; 2955 T; 0 U; 0 Other;

Query Match 11.9%; Score 97; DB 2; Length 8310;
Best Local Similarity 48.9%; Pred. No. 0.0008;
Matches 291; Conservative 0; Mismatches 300; Indels 4; Gaps 1;

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Qy       160 TATGTCGAAGTATTTTCATGGAAGGTGTTAAGAATTAATGTTATTGGGATTACTAATTTC 219
Db      4944 TTTTTTAAATTATAAAAATTTATGAATTAAAAAATATTTAATATATAAATCCTTTTTATA 4885

Qy       220 TAGTATTAATTGTGGTTTGGAAGTTAATATATAATTATTCAATCCTTGTTTTTTATTTTT 279
Db      4884 AATCCTTTTAATTTTCTTGTATGTCATTATATTATATATATATATATATATATATATATA 4825

Qy       280 TTTTTATAACACAATTACAAATAATTTATTTAACTTTGGTTGTTTTCAATTTATGACGGT 339
Db      4824 TATATATATATATATATTGAATAGTTTATATATTTTTATTTTTATTTGACTAATTTAAAT 4765

Qy       340 TAATATTTTAGTTTAATAATTGAGCATTATTATATATTAAATAAATAAATCATTGTAATA 399
Db      4764 TAATTTATATATTTTTTTATTAATATATAAATTATACAAATTATGTAATTTATTTTAATA 4705

Qy       400 TATGTAAAAATAATTTAAAATATAAATTTATTAATATATATAATAAACTCAATCAAACAA 459
Db      4704 TGT----AAATTACCTTTATTTTAATTAAATAAATGAATAAAATTTGAATATTTAATGTT 4649

Qy       460 TAAAAAGATAATAAATTCTTAAATATATAAATTTTTTAAAATAGCTTTTCAGTAAATCTG 519
Db      4648 TTTAGGAAAAAAAACATGTTAATATTTTTATTTTAACTATAAAAAATATTTAGTAAATAAG 4589

Qy       520 TCAAACAATAGAAAATATTTTTTGCAGGTTCATCCAAACACCAGAAAAGTAAATCATTTT 579
Db      4588 TTTTTCAATATCAATTATATAAATGAGGAAAATTAAATAAATTAATATGTAAATTAGTTA 4529
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Qy        580 CAGAAAAGTAAATCATTTTTCAGAAATTATTTTTCGGAAATTATTTTACTGGCAAACAAA 639
              | | || | | |   | |     |   | || ||   | |||||||  |    ||  ||
Db       4528 TATATAAATTATTTTATGTAATTGATAAAATTATCTACATTTATTTTTATATATAAATAA 4469

Qy        640 TGGAGTCTAAGTGTTTCTGTTTTTATTTTTTATTTTTCTATTTAGAGAAACTAGAAATTG 699
              || |          |||  | |     |       || ||  |     |      || ||
Db       4468 TGAAAAAGTTTATTTTAATTATAACAAGTAATAAATTTTAAATTTTAGATTAGTTAAATG 4409

Qy        700 ATTTGTCAAATGTCTTTAATCTAGCTTGTTTAGATTAGTTGAAGGGCACAGAACC 754
              | | | |||| |  ||||| |    |   |||||| | | |     | | || |
Db       4408 TTATTTTAAATCTACTTAATTTTCATAAATTAGATAAAATAATTTTAAAATAATC 4354
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